PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

**(PCT Article 36 and Rule 70)**

| Applicant's or agent's file reference<br>1843.020PC01 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No.<br>PCT/US03/30238 | International filing date *(day/month/year)*<br>26 September 2003 (26.09.2003) | Priority date *(day/month/year)*<br>27 September 2002 (27.09.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>IPC(7): A61K 39/00, 39/385, 39/44 and US Cl.: 530/350, 402; 424/185.1, 178.1, 193.1 | | |
| Applicant<br>VACCINEX, INC. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 27 April 2004 (27.04.2004) | 11 April 2005 (11.04.2005) |
| Name and mailing address of the IPEA/US<br>Mail Stop PCT, Attn: IPEA/ US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Authorized officer<br>Marianne DiBrino, Ph.D.<br>Telephone No. 571-272-1600 |

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30238

## I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-107 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 108-113 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the drawings:
pages 1-3 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the sequence listing part of the description:
pages 1-34 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30238

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. Claims 10-48 were not examined because they were not searched in Chapter 1.

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 10-48 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 10-48 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/30238

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. STATEMENT

| | | |
|---|---|---|
| Novelty (N) | Claims 1-9 | YES |
| | Claims NONE | NO |
| Inventive Step (IS) | Claims 5 and 6 | YES |
| | Claims 1-4 and 7-9 | NO |
| Industrial Applicability (IA) | Claims 1-9 | YES |
| | Claims NONE | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-4 and 7-9 lack an inventive step under PCT Article 33(3) as being obvious over obvious in view of US 2002/0071842 A1 in view of WO 01/78768 A2.

US 2002/0071842 A1 discloses CD1d-IgG multimers further comprising lipid or glycolipid antigen for use in targeting T cells. US 2002/0071842 A1 discloses that an antigen for CD1d is a-GalCer, and that CD1d/antigen complexes are recognized by Tcells. US 2002/0071842 A1 discloses multimerizing CD1d/antigen/IgG using avidin/biotin. US 2002/0071842 A1 discloses using the multimers in vaccine formulations to treat autoimmunity, cancer or infectious diseases.

US 2002/0071842 A1 does not disclose wherein the antibody or fragment thereof is specific for a cell surface marker, nor wherein the antibody is a F(ab) or an F(ab')2 or a full-length antibody.

WO 01/78768 A2 teaches a targeted vaccine delivery system comprising one or more MHC/peptide antigen complexes (recognized by T cells) linked to an antibody which is specific for a cell surface marker such as a T cell surface marker, and use in treating cancer, infectious disease, autoimmune disease and/or allergies. WO 01/78768 A2 further teaches F(ab), full length antibodies or F(ab')2 (especially Abstract and page 24).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used an antibody to a T cell surface marker as taught by WO 01/78768 A2 for MHC/peptide/antibody or fragment thereof multimeric complexes in the complexes disclosed by US 2002/0071842 A1 for CD1d/lipid antigen/IgG multimeric complexes.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to more effectively target CD1d/peptide complexes to T cells since US 2002/0071842 A1 teaches targeting T cells and WO 01/78768 A2 teaches using antbodies or fragments thereof to target another complex recognized by T cells, i.e., MHC/peptide complexes, to T cells or other cells such as tumor targets.

Claims 5 and 6 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest modified a-GalCer antigens recited in the said claims.

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.